

Remarks/Arguments:

I. Status

The Office Action dated on August 18, 2010 (the “Office Action”), has been carefully reviewed. Claims 17, 24, 28, 37, and 41 have been amended. Accordingly, claims 17-43 are pending in this application and claims 17-23 have been withdrawn from examination. Reconsideration of this application is respectfully requested.

II. 35 U.S.C. §102 Rejections

Claims 24, 33 and 34 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,721,104 to Kaufman (hereinafter “Kaufman”), and claims 24, 27, 28, 31-34, and 36 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,275,603 to Ferrante (hereinafter “Ferrante”). Reconsideration of these claims in view of the following remarks is respectfully requested.

A. Claims 24, 33, and 34 are Patentable over Kaufman

Discussion re: Claim 24

1. Claim 24

Claim 24, as amended, recites:

A system for establishing a gap between a femur and a tibia at a knee joint, comprising:

an instrument having (i) a positioning member that defines a femur facing side and a tibia facing side, said positioning member including a first coupler, and (ii) a connector member having a first mating feature;

an augment having a second coupler that cooperates with said first coupler to fix said augment to said positioning member abutting either said femur facing side or said tibia facing side; and

a femoral resection guide having a second mating feature that mates with said first mating feature of said instrument, the instrument, augment, and femoral resection guide configured such that when the system is assembled and the femoral resection guide is positioned on a femur, the instrument and the augment span a gap between the femur and a tibia.

As amended, claim 24 requires a configuration that results in the instrument and augment spanning a gap between a femur and a tibia when the femoral guide is positioned on a femur.

2. Kaufman's Device is Not Arranged as Required by Claim 24

The Examiner has alleged that the device of Kaufman anticipates claim 24. (Office Action at page 3). The device of Kaufman is not arranged in the manner required by claim 24.

Specifically, the Examiner has alleged that the femoral trial component 5 is an “augment”, that the component 61 is an “instrument” and that the component 60 of is a femoral cutting guide. (Office Action at page 3). While the Examiner’s construction of the claim terms is clearly unreasonable, even with that unreasonable construction, the device of Kaufman is configured such that when the component of 60 is mounted to a bone and the device is assembled, the alleged instrument and augment are located between the component 60 and the bone. (See Kaufman at FIG. 1).

A device configured such that an instrument and augment are located between a guide and the bone on which the guide is mounted in not the same as a device configured such that an instrument and augment span a gap between a bone on which a guide is mounted and another bone. Therefore, the alleged guide, instrument, and augment are not arranged in the manner required by claim 24.

3. Conclusion

The Federal Circuit has stated:

Because the Hallmark of anticipation is prior invention, the prior art reference—in order to anticipate under 35 U.S.C. § 102—must not only

disclose all elements of the claim within the four corners of the document, but must also disclose those elements “arranged as in the claim.”

Net Moneyin, Inc. v. Verisign, Inc., 88 USPQ2d 1751, 1758, (Fed. Cir. 2008), citing, *Connell v Sears, Roebuck & Co.*, 722 F.2d 1542, 1548, 220 USPQ 193, 198 (Fed. Cir. 1983). Because the device of Kaufman is not arranged in the manner required by claim 24, Kaufman does not anticipate claim 24.

Anticipation under 35 U.S.C. § 102 is proper only if the prior art reference discloses each and every element of the claim. Since Kaufman does not disclose all of the elements of claim 24 arranged in the manner required by claim 24, Kaufman does not anticipate claim 24.

Discussion re: Claims 33 and 34

Claims 33 and 34 were rejected based upon the same prior art discussed above with respect to claim 24. Each of claims 33 and 34 depend from claim 24 and include all of the limitations discussed above with respect to claim 24, along with additional limitations. Therefore, for at least the reasons set forth above with respect to claim 24, claims 33 and 34 are patentable over the prior art.

B. Claims 24, 27, 28, and 31-34 are Patentable over Ferrante

Discussion re: Claim 24

1. Claim 24

As noted above, claim 24 requires a configuration that results in the instrument and augment spanning a gap between a femur and a tibia when the femoral guide is positioned on a femur.

2. Ferrante's Device is Not Arranged as Required by Claim 24

The Examiner has alleged that the device of Ferrante anticipates claim 24. (Office Action at page 3). The device of Ferrante is not arranged in the manner required by claim 24.

Specifically, the Examiner has alleged that the alignment pin 31 is an “augment”, the trial base 26 is an instrument, and the guide means including slots 44 and plates 46 is a “femoral guide”. (Office Action at page 3). While the Examiner’s construction of the claim terms is clearly unreasonable, even with that unreasonable construction, the device of Ferrante is configured such that when the guide means is mounted to a bone and the device is assembled, the alleged instrument and augment are located between the guide means and the bone. (See Ferrante at FIG. 3).

A device configured such that an instrument and augment are located between a guide and the bone on which the guide is mounted is not the same as a device configured such that an instrument and augment span a gap between a bone on which a guide is mounted and another bone. Therefore, the alleged guide, instrument, and augment are not arranged in the manner required by claim 24.

3. Conclusion

The Federal Circuit has stated:

Because the Hallmark of anticipation is prior invention, the prior art reference—in order to anticipate under 35 U.S.C. § 102—must not only disclose all elements of the claim within the four corners of the document, but must also disclose those elements “arranged as in the claim.”

Net Moneyin, Inc. v. Verisign, Inc., 88 USPQ2d 1751, 1758, (Fed. Cir. 2008), citing,

Connell v Sears, Roebuck & Co., 722 F.2d 1542, 1548, 220 USPQ 193, 198 (Fed. Cir.

1983). Because the device of Ferrante is not arranged in the manner required by claim 24, Ferrante does not anticipate claim 24.

Anticipation under 35 U.S.C. § 102 is proper only if the prior art reference discloses each and every element of the claim. Since Ferrante does not disclose all of the elements of claim 24 arranged in the manner required by claim 24, Ferrante does not anticipate claim 24.

Discussion re: Claims 27 and 33-34

Claims 27 and 33-34 were rejected based upon the same prior art discussed above with respect to claim 24. Claims 27 and 33-34 depend from claim 24 and include all of the limitations discussed above with respect to claim 24, along with additional limitations. Therefore, for at least the reasons set forth above with respect to claim 24, claims 27 and 33-34 are patentable over the prior art.

Discussion re: Claim 28

1. Claim 28

Claim 28, as amended, recites:

A system for establishing a gap between a femur and a tibia at a knee joint, comprising:

an instrument having a positioning member that includes a first coupler, said positioning member defining (i) a femur facing side, (ii) a tibia facing side, and (iii), a guide slot configured to receive an intramedullary pin;

an augment having a second coupler that cooperates with said first coupler to fix said augment to said positioning member abutting either said femur facing side or said tibia facing side; and

an intramedullary pin received within said guide slot of said positioning member of said instrument by movement of the guide slot relative to the intramedullary pin along an axis substantially parallel to at least one of the femur facing side and tibia facing side.

As amended, claim 28 requires a configuration that allows the intramedullary pin to be received into the guide slot by movement along an axis substantially parallel to the femur or tibia facing surface.

2. Ferrante's Device is Not Arranged as Required by Claim 28

The Examiner has alleged that the device of Ferrante anticipates claim 28. (Office Action at page 3). Claim 28 has been amended to clarify the orientation of the slot. The alleged slot is not configured in the manner required by claim 28.

Specifically, the Examiner has alleged that the runner 28 and aperture 29 of Ferrante are a guide slot. (Office Action at page 3). While the Examiner's construction of the claim terms is clearly unreasonable, even with that unreasonable construction, the device of Ferrante is configured such that the intramedullary pin is received into the alleged guide slot by movement along an axis substantially perpendicular to the alleged femur and tibia facing surfaces of the tibial trial base 26. (See Kaufman at FIG. 1).

A device configured such that a pin is inserted into a slot by movement in a direction perpendicular to a surface is not the same as a device configured such that a pin is inserted into a slot by movement in a direction substantially parallel to a surface. Therefore, the alleged guide, instrument, and augment are not arranged in the manner required by claim 28.

3. Conclusion

The Federal Circuit has stated:

Because the Hallmark of anticipation is prior invention, the prior art reference—in order to anticipate under 35 U.S.C. § 102—must not only disclose all elements of the claim within the four corners of the document, but must also disclose those elements “arranged as in the claim.”

Net Moneyin, Inc. v. Verisign, Inc., 88 USPQ2d 1751, 1758, (Fed. Cir. 2008), citing, *Connell v Sears, Roebuck & Co.*, 722 F.2d 1542, 1548, 220 USPQ 193, 198 (Fed. Cir. 1983). Because the device of Ferrante is not arranged in the manner required by claim 28, Ferrante does not anticipate claim 28.

Anticipation under 35 U.S.C. § 102 is proper only if the prior art reference discloses each and every element of the claim. Since Ferrante does not disclose all of the elements of claim 28 arranged in the manner required by claim 28, Ferrante does not anticipate claim 28.

Discussion re: Claims 31-32 and 36

Claims 31-32 and 36 were rejected based upon the same prior art discussed above with respect to claim 28. Claims 31-32 and 36 depend from claim 28 and include all of the limitations discussed above with respect to claim 28, along with additional limitations. Therefore, for at least the reasons set forth above with respect to claim 28, claims 31-32 and 36 are patentable over the prior art.

III. 35 U.S.C. §103 Rejections

Discussion re: Claims 25 and 26

Claims 25 and 26 were rejected under 35 U.S.C. §103 as being unpatentable over Ferrante in view of U.S. Patent No. 5,931,838 of Vito (hereinafter “Vito”). Claims 25

and 26 depend from amended claim 24. As explained above, Ferrante does not anticipate parent claim 24, so this reference cannot serve as a basis for an obviousness rejection of dependent claims 25 and 26. Moreover, there is no rational basis for placing an O-ring in the alleged bore of Ferrante since the alleged augment, alignment pin 31, is driven into the bone which provides anchoring of the alignment pin 31. There is simply no *prima facie* showing of obviousness of claims 25 and 26 in view of Ferrante. Therefore, claims 25 and 26 are patentable over Ferrante.

Discussion re: Claims 29 and 30

Claims 29 and 30 were rejected under 35 U.S.C. §103 as being unpatentable over Ferrante in view of Vito. Claims 29 and 30 depend from amended claim 28. As explained above, Ferrante does not anticipate parent claim 28, so this reference cannot serve as a basis for an obviousness rejection of dependent claims 29 and 30. Moreover, there is no rational basis for placing an O-ring in the alleged bore of Ferrante since the alleged augment, alignment pin 31, is driven into the bone which provides anchoring of the alignment pin 31. There is simply no *prima facie* showing of obviousness of claims 29 and 30 in view of Ferrante. Therefore, claims 29 and 30 are patentable over Ferrante.

Discussion Re: Patentability of Claim 37

Claim 37 has been amended to recite that “the instrument, augment, and femoral resection guide are configured such that when the system is assembled and the femoral resection guide is positioned on a femur, the instrument and the augment span a gap between the femur and a tibia.” For purposes of this discussion, this is the same limitation discussed above regarding the patentability of claim 24 over Ferrante. Claim

37 was rejected based primarily upon Ferrante with further reference to Vito for an O-ring. As explained above, Ferrante does not anticipate claim 24, so this reference cannot serve as a basis for an obviousness rejection of claim 37. Moreover, there is no rational basis for placing an O-ring in the alleged bore of Ferrante since the alleged augment, alignment pin 31, is driven into the bone which provides anchoring of the alignment pin 31. There is simply no *prima facie* showing of obviousness of claim 37 in view of Ferrante. Therefore, claim 37 is patentable over Ferrante.

Discussion re: Claims 38-40

Claims 38-40 were rejected based upon the same prior art discussed above with respect to claim 37. Claims 38-40 depend from claim 37 and include all of the limitations discussed above with respect to claim 37, along with additional limitations. Therefore, for at least the reasons set forth above with respect to claim 37, claims 38-40 are patentable over the prior art.

Discussion Re: Patentability of Claim 41

Claim 41 has been amended to recite “an intramedullary pin received within said guide slot of said positioning member of said instrument by movement of the guide slot relative to the intramedullary pin along an axis substantially parallel to at least one of the femur facing side and tibia facing side.” For purposes of this discussion, this is the same limitation discussed above regarding the patentability of claim 28 over Ferrante. Claim 41 was rejected based primarily upon Ferrante with further reference to Vito for an O-ring. As explained above, Ferrante does not anticipate claim 28, so this reference cannot serve as a basis for an obviousness rejection of claim 41. Moreover, there is no rational

basis for placing an O-ring in the alleged bore of Ferrante since the alleged augment, alignment pin 31, is driven into the bone which provides anchoring of the alignment pin 31. There is simply no *prima facie* showing of obviousness of claim 41 in view of Ferrante. Therefore, claim 41 is patentable over Ferrante.

Discussion re: Claims 42-43

Claims 42-43 were rejected based upon the same prior art discussed above with respect to claim 41. Claims 42-43 depend from claim 41 and include all of the limitations discussed above with respect to claim 41, along with additional limitations. Therefore, for at least the reasons set forth above with respect to claim 41, claims 42-43 are patentable over the prior art.

IV. Conclusion

Applicants respectfully request entry of the amendments and favorable consideration of the application.

A prompt and favorable action on the merits is requested.

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